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(21) International Application Number: PCT/US99/01368 (22) International Filing Date: 21 January 1999 (21.01.99) (30) Priority Data: 09/012,520 23 January 1998 (23.01.98) US (71) Applicant: MEDTRONIC, INC. [US/US]; 7000 Central Avenue Northeast, Minneapolis, MN 55432 (US). (72) Inventors: BRISCOE, Roderick, E.; 5271 14 Mile Court Northeast, Rockford, MI 49341 (US). ROM, Paul, F.; 1423 Mapleview Southeast, Kentwood, MI 49508 (US). STAPERT, Karyl, L.; 2420 Leonard Northwest, Grand Rapids, MI 49504 (US). DE WINDT, David, B.; 1907 Forrester Southeast, Grand Rapids, MI 49508 (US). DE VRIES, Ronald, A.; 9544 Perry Street, Zeelan, MI 49464 (US). GUNDRY, Steven, R.; 30759 East Sunset Drive South, Redlands, CA 92373 (US). SIDOR, William, E., Jr.; 8601 Kreuter Northeast, Rockford, MI 49341 (US). (74) Agents: FORREST, Peter et al.; Medtronic, Inc., 7000 Central Avenue Northeast, MS301, Minneapolis, MN 55432 (US).		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: FLEXIBLE CANNULA OBTURATOR <div style="text-align: center;"> </div> (57) Abstract <p>An obturator for a cannula includes an elongate member and a flexible disc. The cannula has proximal and distal ends and a lumen extending therebetween. The distal end of the cannula has a circular cross section. The cannula also includes a first portion having a non-circular cross section and at least one fluid aperture formed adjacent the distal end. The flexible disc of the obturator is coupled to a distal end of the elongate member, both of which are adapted to be telescopically received in the lumen of the cannula. The flexible disc is configured to restrict the flow of fluid, entering the at least one fluid aperture, through the lumen.</p>		

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FLEXIBLE CANNULA OBTURATOR

CROSS-REFERENCE TO RELATED APPLICATION

5 The present application is a continuation-in-part of U.S. Patent Application Serial No. 08/780,995, filed on January 9, 1997.

BACKGROUND OF THE INVENTION

Field of the Invention

10 This invention relates to cannulas and, more particularly, to a cannula which is oval-shaped in cross-section and therefore ideally suited for use in minimally invasive surgical procedures.

Description of the Related Art

15 Cannulas have a wide variety of applications during surgical procedures. For example, in coronary surgery, venous and arterial cannulas are used to conduct blood between the body and bypass equipment. Cannulas are used to conduct cardioplegia solution for both antigrade and retrograde solution administration, and cannulas are also used as vents, sumps, and for chest tube fluid suction. The structure for these known cannulas generally comprises a cannula
20 body which is circular in cross-section and has at least one lumen extending therethrough which is similarly circular in cross-section. Examples of these structures are seen in U.S. Patent Nos. 4,639,252, 4,129,129 and 5,395,330.

25 A recent trend in surgical procedures is to minimize the size of the access apertures formed in the chest cavity. These procedures include mini-sternotomy and minimally invasive cardiac surgery. In each of these procedures, the goal is to reduce the size of the aperture in the chest wall. One problem in achieving this goal is the size, geometry, and space requirements for the instruments, cannulas, and the like which must pass through the reduced size apertures.

SUMMARY OF THE INVENTION

5 The cannula according to the invention overcomes the problems of the prior art by providing a cannula having a prescribed geometry, which more efficiently occupies the space of the aperture without adversely affecting the fluid rate therethrough, and an obturator for use with the cannula.

10 In accordance with one embodiment of the invention, an obturator for a cannula is provided. The cannula has proximal and distal ends, and a lumen extending therebetween. The distal end of the cannula is circular in cross-section. The cannula further includes a first portion having a non-circular cross-section and at least one fluid aperture formed adjacent the distal end. The obturator includes an elongate member and a flexible disc which is coupled to a distal end of the elongate member. The elongate member and flexible disc of the obturator are adapted to be telescopically received in the lumen of the cannula, and the flexible disc is
15 configured to restrict the flow of fluid, entering the at least one fluid aperture, through the lumen.

In another embodiment of the invention, a cannula assembly includes a cannula and an obturator. The cannula has proximal and distal ends, a lumen, a first portion, and at least one fluid aperture as described above. The obturator,
20 which is telescopically received in the cannula lumen, includes an elongate member and a flexible disc. The flexible disc substantially restricts the flow of fluid, entering the at least one fluid aperture, through the lumen, when the obturator is fully inserted in the cannula.

25 The invention is also directed to a method of positioning a fluid conducting cannula in a body. The method includes the steps of providing a cannula, such as that described above, and inserting an obturator in the lumen of the cannula. The obturator includes an elongate member and a flexible disc coupled to a distal end of the elongate member. The flexible disc substantially restricts the flow of fluid, entering the at least one fluid aperture, through the lumen of the
30 cannula. The method further includes the steps of providing a percutaneous

aperture in a body, inserting the distal end of the cannula in the percutaneous aperture, and positioning the cannula so that the first portion thereof extends through the percutaneous aperture.

5 The invention is further directed to a method of positioning a fluid conducting cannula in a body, including the step of providing a pre-assembled cannula assembly. The pre-assembled cannula assembly has includes a cannula, as described above, and an obturator disposed in the lumen of the cannula. The method further includes the steps of providing a percutaneous aperture in a body, inserting the distal end of the pre-assembled cannula assembly into the body through
10 the percutaneous aperture, and positioning the cannula so that the first portion extends through the percutaneous aperture.

Other advantages of the invention will become apparent from the detailed description given hereinafter. It should be understood, however, that the detailed description and specific embodiments are given by way of illustration only,
15 since, from this detailed description, various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art.

BRIEF DESCRIPTION OF THE DRAWINGS

20 The invention will now be described with reference to the drawings in which:

FIG. 1 is a perspective view of a venous cannula assembly wherein at least a portion of the cannula body is oval in cross-section;

FIG. 2 is a cross-sectional view taken generally along the line 2-2 of FIG. 1 showing the oval cross-section of the cannula body;

25 FIG. 3 is a plan view of a patient showing a cannula according to the invention passing through a mini-thoracotomy;

FIG. 4 is a perspective view of a second embodiment of the cannula wherein at least two portions of the cannula body are oval in cross-section and the oval sections are not aligned with one another;

FIG. 5 is a cross-sectional view taken generally along the line 5-5 of FIG. 4 showing the oval cross-sections of the second embodiment of the cannula body;

FIG. 6 is a plan view of a second embodiment of the obturator for the cannula assembly;

FIG. 7 is a plan view of a third embodiment of the obturator;

FIG. 8 is a partial cross-sectional view of the cannula of FIG. 1 with a fourth embodiment of the obturator for the cannula assembly, showing the obturator fully inserted in the cannula;

FIG. 9 is a cross-sectional view taken generally along the line 9-9 of FIG. 8;

FIG. 10 is a partial cross-sectional view of the cannula of FIG. 1 showing the fourth embodiment of the obturator partially retracted;

FIG. 11 is a cross-sectional view taken generally along the line 11-11 of FIG. 10;

FIG. 12 is a plan view of the obturator shown in FIGS. 8-11 and including a malleable, stainless steel sleeve; and

FIG. 13 is a cross-sectional view taken generally along the line 13-13 of FIG. 12.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now to the drawings and to FIGS. 1 and 2 in particular, a first embodiment of the cannula assembly according to invention is shown. The first embodiment of the cannula assembly 12 comprises a cannula 14 and an obturator 16 which is selectively, telescopically received in the cannula 14. The cannula 14 comprises a cannula body 18 having a proximal end 20, a distal end 22, and a lumen 24 extending between the proximal and distal ends. A conventional luer connector 26 is preferably provided on the proximal end 20, and the distal end 22 preferably includes at least one fluid inlet aperture for the receipt of fluid into the lumen. A helically wound reinforcing spring 38 is preferably, integrally formed into

the cannula body 18. The cannula seen in FIGS. 1 and 2 includes a first set of fluid apertures 28 formed immediately adjacent the distal end 22 and a second set of apertures 30 formed a spaced distance proximally from the distal end. This structure is ideally suited for use as a venous cannula during a cardiac surgical procedure.

One unique feature of the cannula assembly according to the invention is that at least a portion of the cannula body 18 is non-circular. This first non-circular portion 32 is preferably oval in cross-section and is defined by a major cross-sectional axis 34 and a minor cross-sectional axis 36. As will be described further below, the incorporation of a non-circular portion 32 makes the cannula assembly according to the invention ideally suited for use in minimally invasive cardiac surgical procedures.

The obturator 16 comprises a proximal end 48 and a distal end 50. The obturator is adapted to be slidably, telescopically received inside the lumen 24 of the cannula 14. When the obturator is fully received inside the cannula lumen 24, the obturator substantially seals the second set of fluid apertures 30 so that fluid cannot enter the lumen 24 from the first set of fluid apertures 28 and then egress into the operation field through these apertures.

The cannula assembly 12 described above is ideally suited for use as a venous cannula during a coronary surgical procedure similar to the cannula described in U.S. Patent No. 4,129,129 which is expressly incorporated herein by reference. In use, the cannula 14, with the obturator 16 fully received therein, is inserted through an appropriate incision into the right atrium and the inferior vena cava. As the distal end 22 of the cannula 14 is inserted into the blood flow passing through the right atrium and inferior vena cava, blood will enter the first set of fluid apertures 28, but the obturator 16 will restrict the flow of blood through the lumen 24 to the second set of fluid apertures 30. Once the cannula 14 is properly positioned, the obturator 16 is removed from the cannula 14, and the luer connector 26 of the cannula 14 is connected to a conventional bypass system. With the

cannula 14 in this position, blood enters the lumen 24 through both the first and second fluid apertures 28, 30 and is conducted to the bypass machine.

5 Traditional cardiac surgery is typically performed by a median sternotomy in which substantially the entire chest cavity is exposed by cutting the full length of the sternum and spreading back the sternum and ribs to expose the entire pericardium. However, a recent trend in cardiac surgery is to attempt to minimize the size of the access apertures formed in the patient's chest using techniques such as a right or left anterior thoracotomy, mini-sternotomy, and multi-
10 port access apertures. In each of these procedures, the size of the access aperture formed in the patient's chest is considerably smaller than the traditional median sternotomy, thereby reducing the complications and possible side effects associated with such a massive wound. However, reducing the size of the access aperture raises a new set of problems not encountered in the conventional median sternotomy, namely, sufficient space for the receipt of all the instruments and
15 equipment.

One limiting factor to reducing the size of the access aperture in any surgical procedure is the cross-sectional space requirements of the surgical tools which must be inserted through the access aperture. The cannula according to the invention is an improvement over the known cannulas because it more efficiently
20 utilizes the limited space of the access aperture without adversely affecting the fluid flow characteristics through the cannula.

As seen in FIGS. 1-3, at least a portion 32 of the cannula body 18 is oval in cross-section, and the cannula body 18 is received in an access aperture 52 formed in the chest wall 54 of the patient 56. In this example, the access aperture
25 52 comprises a right anterior thoracotomy. Preferably, the proximal 20 and distal 22 ends of the cannula 14 are circular in cross-section while the central portion of the cannula body 18 is oval in cross-section. When the oval portion 32 of the cannula is positioned in the access aperture 52, the available cross-sectional area of the access aperture 52 is used more efficiently. Preferably, the cannula is
30 positioned so that the minor cross-sectional axis 36 extends radially inwardly from

the sidewall of the access aperture 52. With this structure, the cannula 14 extends a minimum distance inwardly toward the center of the access aperture 52 thereby utilizing the available space more efficiently. If a traditional cannula having a round cross-section with a flow rate potential comparable to the oval-shaped cannula according to the invention were positioned in the access aperture 52, then the diameter of the round cannula would extend farther toward the center of the access aperture 52 and utilize the valuable cross-sectional area of the opening far more inefficiently.

While the preferred embodiment of the cannula 14 and cannula assembly 12 described above is a venous cannula, it is to be understood that the invention extends to any cannula inserted into the body through an access aperture including but not limited to an arterial cannula, a cardioplegia cannula (both retrograde and antigrade), a vent, a sump, or a suction tube. Similarly, FIG. 3 shows use of a cannula in a right anterior thoracotomy. It is to be understood that the benefits of the invention can be realized regardless of the particular surgical aperture which is created.

FIGS. 4 and 5 show a second embodiment of the cannula according to the invention. In this embodiment, the cannula 64 also includes a second non-circular portion 66. Preferably, the second non-circular portion is oval in cross-section and has a major cross-sectional axis 68 and a minor cross-sectional axis 70 with the major cross-sectional axes 34, 68, respectively, of the first and second non-circular portions 32, 66 not being parallel to one another and preferably perpendicular to one another. With this structure, the first non-circular portion 32 can be positioned to extend through the access aperture 52 as described above, and the second non-circular portion 66 can be positioned either inside the body or outside the body in a particular position which requires significant bending or deflection of the cannula 64.

A second embodiment of the obturator 76 is shown in FIG. 6. When the cannula is used as a venous cannula during a cardiac surgical operation, it is preferred to include an obturator which substantially seals the second set of fluid apertures 30

from the first set of fluid apertures 28 during the initial insertion of the cannula 14 in to the blood flow. In the preferred embodiment of the cannula 14, the minor cross-sectional axis 36 of the non-circular portion 32 is less than the interior diameter of the distal end 22 of the cannula 14. Therefore, in order for the obturator to be telescopically inserted and removed from the lumen, whatever means are incorporated onto the obturator must be pliable or radially expandable to accommodate these diametrical constraints. In this embodiment, an expandable member such as a conventional, silicone balloon 78 is provided on the distal end 50 of the obturator 76. The obturator 76 comprises a proximal end 80 and a distal end 82. The balloon 78 is fluidly connected to an inflation lumen 84 which extends from the balloon 78, to the proximal end of the obturator. Preferably, a luer connector 86 is mounted to the terminal end of the inflation lumen 84.

The balloon is adapted for inflation from a retracted state as seen in FIG. 6 to an expanded state which extends radially outwardly from the obturator 76 a sufficient distance to substantially seal the second set of fluid apertures 30. In use, the obturator 76 is inserted into the lumen 24 with the balloon 78 in the retracted state. Once the distal end 82 of the obturator 76 is received in the lumen 24 so that the balloon 78 is positioned immediately adjacent the second set of fluid apertures 30, the balloon 78 is inflated through the flow of pressurized fluid through the inflation lumen 84 and connector 86. The balloon 78 is inflated a sufficient amount to substantially seal the fluid apertures 30. Once the cannula assembly 12 is properly positioned in the blood flow, the balloon 78 is deflated by removing the pressurized fluid from the balloon 78 through the inflation lumen 84 and connector 86. Once the balloon 78 is sufficiently deflated, then the obturator 76 is removed from the cannula lumen 24, and the lumen is fluidly connected to the bypass system.

A third embodiment of the obturator 90 is shown in FIG. 7. Similar to the earlier embodiments, this embodiment of the obturator 90 comprises a proximal end 92 and a distal end 94. However, in this embodiment, an expandable foam member 96 is mounted on the distal end 94 of the obturator 90. In the relaxed

state, the diameter of the foam member 96 is slightly larger than the interior diameter of the cannula 14 at the second set of fluid apertures 30. Therefore, when the foam member 96 is positioned immediately adjacent the apertures 30, the foam member will substantially seal the apertures 30 from the lumen 24.

5 In the third embodiment, the foam member 96 is formed from a soft, pliable foam which can easily be compressed by the opposed sidewalls of the cannula in the non-circular portion as the obturator 90 passes therethrough. Once the obturator 90 is fully received in the lumen 24, the foam member 96 expands outwardly a sufficient distance to substantially seal the fluid apertures 30. Similar
10 to the earlier embodiments, once the cannula assembly 12 is properly positioned, then the obturator is telescopically removed from the lumen. As the obturator is being pulled through the non-circular portions, the opposed sidewalls of the lumen will compress the foam member a sufficient distance to permit passage of the foam member therethrough.

15 A fourth embodiment of the obturator 100 for a cannula 14 is shown generally in FIGS. 8-13. As with the earlier embodiments, the obturator 100 has a proximal end 102 and a distal end 104. The obturator 100 includes an elongate member 106 and a flexible disc 108, which is coupled to the distal end 104 of the elongate member 106. The flexible disc 108 is preferably, but not necessarily, thin.
20 In the present embodiment of the invention, the flexible disc 108 is round and has a diameter substantially equal to the diameter of the lumen 24 at the distal end 22 of the cannula body 18. However, it should be noted that the flexible disc 108 may have a non-circular shape, provided that its shape corresponds to that of the lumen 24 at the distal end 22. As illustrated in FIG. 9, when the obturator 100 is fully
25 inserted into the cannula lumen 24, the flexible disc 108 substantially seals the distal end of the lumen 24 to prevent the flow of blood, which enters through the first set of fluid apertures 28, from passing through the lumen 24 to the second set of fluid apertures 30. After the cannula 14 is inserted into a blood vessel, the obturator 100 is removed, allowing blood to flow through the first and second sets of fluid
30 apertures 28 and 30, respectively, and into the lumen 24.

The flexible disc 108 is formed from a durable material which is sufficiently flexible that the edges of the disc 108 bend, enabling the disc 108 to pass through the first non-circular portion 32 of the cannula body 18, as shown in FIG. 10, and is also sufficiently stiff to occlude the distal end 22 of the lumen 24 when the cannula 14, with the obturator 100 inserted therein, is positioned in a body. The flexible disc 108 is preferably made of polypropylene or polyethylene but may also be made of other materials, such as foam, teflon, or other plastics.

As shown in FIGS. 9 and 11, the flexible disc 108 further includes a feature 109 for allowing air to escape from the proximal end 20 of the cannula 14. Preferably, the feature 109 is at least one tiny notch 110 formed in the flexible disc 108. The present obturator 100 has two notches 110 located along the edge of the flexible disc 108 and diametrically opposed from each other. However, any number of notches may be provided on the flexible disc 108. The feature 109 may also be apertures (not shown) formed in an interior region of the disc 108, rather than notches disposed along the edge. The notches 110 prevent air in the distal end 22 of cannula 14 from being introduced into a vein or artery, when the cannula 14 is inserted therein. The notches 110 are sufficiently small to enable air in the distal end 22 of the cannula lumen 24 to escape out the proximal end 20, while preventing blood from doing the same. As the cannula 14 is inserted into a chamber of the heart or vessel, pressure from blood entering the first set of fluid apertures 28 forces any air trapped in the distal end 22 of the cannula lumen 24 through the notches 110, enabling air to escape out the proximal end 20 of the cannula 14.

The elongate member 106 of the obturator 100 may be a solid shaft or wire, or a hollow tube. It is preferred that the elongate member 106 and flexible disc 108 are integrally formed as a single piece, such as by injection molding. However, the elongate member 106 and flexible disc 108 may also be separate and distinct pieces, that are coupled together in a conventional manner.

As shown in FIGS. 12 and 13, the obturator 100 may include a sleeve 112 that is injection molded directly therein. The sleeve 112, which is preferably made of a malleable material, such as stainless steel, wraps around the

exterior of the elongate member 106 and extends along at least a portion of the length thereof. Since the sleeve 112 is made of a malleable material, the cannula 14, with the obturator 100 in place, may be bent to a desired configuration, prior to insertion in the body, and will maintain that configuration. In lieu of the sleeve 112, a malleable wire or rod (not shown), disposed inside the elongate member 106, will also provide such a pliable structure.

The obturator 100 preferably further includes a stop 114 and a collar or grip 116 as shown. The stop 114 is located on the elongate member 106, adjacent the proximal end 102, and limits the depth of insertion of the obturator 100 in the cannula lumen 24 to prevent damage to either the flexible disc 108 or the distal end 22 of the cannula 14. In the preferred embodiment of the obturator 100, the stop 114 is conical in shape and includes a flat surface 118 and an inclined surface 120. It should be noted, however, that other configurations for the stop 114 may be envisioned. The inclined surface 120 of the conical stop 114 extends toward the distal end 104 of the elongate member 106, while the flat surface 118 is located proximally of the inclined surface 120. When the obturator 100 is fully inserted in the cannula 14, the stop 114 abuts the proximal end 20 of the cannula 14, with a portion of the inclined surface 120 being received in the cannula lumen 24.

The grip 116 is provided at the proximal end 102 of the obturator 100 and is coupled to the elongate member 106. The grip 116 extends beyond the diameter of the elongate member 106 and enables a user to grasp the obturator 100 and remove it from the cannula 14. The grip 116, stop 114, elongate member 106 and flexible disc 108 of the obturator 100 are preferably injection molded as a single, integral piece. However, as discussed above, two or more pieces of the obturator 100 may be separate and distinct and may be coupled together in a conventional manner.

The flexible disc 108 of the obturator 100, the foam member 96 of the obturator 90, and the expandable balloon 78 of the obturator 76 are only three examples of expandable means provided on the obturator to permit passage of the

distal end of the obturator through the confines of the lumen and still capable of restricting the flow of fluid through the lumen of the catheter. It is understood that any other means which accommodate the varying diameters fall within the scope of the invention.

5 The preferred method for forming the cannula 14 according to the invention comprises the steps of extruding a circular length of tubing. Preferably, tubing is formed from silicone or polyvinyl chloride. Depending upon the particular application, a helically wound spring may be received on the inside of the hollow tube and either be adhesively fastened therein or integrally molded therein.

10 Next, the tubing is cut to the desired length, and then the nonBcircular portion is formed by positioning the length of the tube between two opposed platens and then compressing the two platens a sufficient distance to obtain the desired non-circular or oval-shaped configuration. Once the spring has been plastically deformed, it will retain the pliable cannula body in the oval or non-circular configuration. Finally,

15 the luer connector and flow aperture member are mounted to the proximal and distal ends thereof. The cannula 14 can be compressed to create the non-circular configuration prior to or subsequent to mounting of the elements on the proximal and distal ends thereof. In the event that two different non-circular portions are formed along the length of the cannula, then the step of compressing the cannula

20 body between two opposed platens is repeated, as necessary, for the additional non-circular sections.

 With the rapid evolution of surgical procedures which minimize the size of the access aperture cut into the patient, the known, conventional, surgical tools such as cannulas, vents, sumps, or suction tubes must be adapted to

25 accommodate such advances. The nonBcircular cannula according to the invention is one such modification which assists the surgeons in achieving the goal of minimizing the wound size for a variety of surgical procedures. This advantage is accomplished without adversely affecting the fluid flow rate through the tubing or otherwise adversely affecting the performance of the tubing.

Reasonable variation and modification are possible within the spirit of the foregoing specification and drawings without departing from the scope of the invention.

CLAIMS:**What is Claimed:**

1. An obturator for a cannula having a proximal end, a distal end having a circular cross-section, a lumen extending between the proximal and distal ends, a first portion having a non-circular cross-section, and at least one fluid aperture formed adjacent the distal end, the obturator comprising:
- 5 an elongate member having a proximal end and a distal end; and
a flexible disc coupled to the distal end of the elongate member, the flexible disc and elongate member adapted to be telescopically received in the lumen, and the flexible disc configured to restrict the flow of fluid, entering the at least one fluid aperture, through the lumen.
- 10 2. An obturator according to claim 1, wherein the flexible disc is configured to allow air in the distal end of the cannula to escape out the proximal end while prohibiting fluid from doing so.
- 15 3. An obturator according to claim 2, wherein the flexible disc includes at least one notch formed therein and configured to allow air to escape.
4. An obturator according to claim 1, further comprising a stop adjacent the proximal end of the elongate member, the stop configured to limit the depth to which the obturator is inserted in the lumen.
- 20 5. An obturator according to claim 4, wherein the stop has a substantially conical shape.
- 25

6. An obturator according to claim 1, further comprising a grip for removing the obturator from the cannula.

7. An obturator according to claim 1, wherein the flexible disc is made of plastic.

8. An obturator according to claim 1, wherein the elongate member and flexible disc are integrally formed to each other

9. An obturator according to claim 1, wherein the elongate member includes a malleable material.

10. A cannula assembly for use in conducting fluid to or from a body, the cannula assembly comprising:

a cannula having a proximal end, a distal end and a lumen extending therebetween, the distal end having a circular cross-section, the cannula including a first portion having a non-circular cross-section, and at least one fluid aperture formed adjacent the distal end; and

an obturator telescopically received in the lumen of the cannula, the obturator including an elongate member and a flexible disc, the elongate member having a proximal end and a distal end, the flexible disc coupled to the distal end of the elongate member and substantially restricting the flow of fluid, entering the at least one fluid aperture, through the lumen.

11. A cannula assembly according to claim 10, wherein the first portion of the cannula is oval in cross-section and has a major cross-sectional axis and a minor cross-sectional axis, the length of the minor cross-sectional axis being less than the length of the major cross-sectional axis and also less than the diameter of the distal end

12. A cannula assembly according to claim 11, wherein the diameter of the flexible disc is substantially equal to the diameter of the distal end of the cannula

5 13. A cannula assembly according to claim 10, wherein the flexible disc is configured to allow air in the distal end of the cannula to escape out the proximal end while prohibiting fluid from doing so

10 14. A cannula assembly according to claim 13, wherein the flexible disc includes at least one notch formed therein configured to allow air to escape.

15 15. A cannula assembly according to claim 10, further comprising a stop adjacent the proximal end of the elongate member, the stop abutting the proximal end of the cannula when the obturator is fully inserted in the lumen

16. A cannula assembly according to claim 15, wherein the stop has a substantially conical shape.

20 17. A cannula assembly according to claim 10, further comprising a grip at the proximal end of the obturator for removing the obturator from the cannula.

25 18. A cannula assembly according to claim 10, wherein the elongate member and flexible disc of the obturator are integrally formed to each other.

30 19. A cannula assembly according to claim 10, wherein the obturator is formed by injection molding.

20. A cannula assembly according to claim 10, wherein the elongate member of the obturator includes a malleable stainless steel

21. A method of positioning a fluid conducting cannula in a body,
5 the method comprising the steps of:

providing a cannula having a proximal end, a distal end having a circular cross-section, a lumen extending between the proximal and distal ends, a first portion having a non-circular cross-section, and at least one fluid aperture formed adjacent the distal end;

10 inserting an obturator in the lumen of the cannula, the obturator including an elongate member and a flexible disc, the elongate member having a proximal end and a distal end, the flexible disc coupled to the distal end of the elongate member and substantially restricting the flow of fluid, entering the at least one fluid aperture, through the lumen;

15 providing a percutaneous aperture in a body;

inserting the distal end of the cannula into the body through the percutaneous aperture; and

positioning the cannula so that the first portion extends through the percutaneous aperture.

20 22. A method according to claim 21, further comprising the step of flexing the flexible disc during insertion of the obturator in the first portion of the cannula.

25 23. A method according to claim 21, wherein the obturator includes a stop adjacent the proximal end of the elongate member, and wherein the obturator is inserted in the cannula until the stop abuts the proximal end of the cannula.

24. A method according to claim 21, wherein the obturator includes a grip at the proximal end of the elongate member, and further comprising the step of removing the obturator by the grip after the cannula has been inserted into the percutaneous aperture.

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25. A method of positioning a fluid conducting cannula in a body, the method comprising the steps of:

(a) providing a pre-assembled cannula assembly including:

10 a cannula including a proximal end, a distal end having a circular cross-section, a lumen extending between the proximal and distal ends, a first portion having a non-circular cross-section, and at least one fluid aperture formed adjacent the distal end; and

15 an obturator disposed in the lumen of the cannula, the obturator including an elongate member and a flexible disc, the elongate member having a proximal end and a distal end, the flexible disc coupled to the distal end of the elongate member and substantially restricting the flow of fluid, entering the at least one fluid aperture, through the lumen;

(b) providing a percutaneous aperture in a body;

20 (c) inserting the distal end of the pre-assembled cannula assembly into the body through the percutaneous aperture; and

(d) positioning the cannula so that the first portion extends through the percutaneous aperture.

25 26. A method according to claim 25, further comprising the step of flexing the flexible disc during insertion of the obturator in the first portion of the cannula.

27. A method according to claim 25, wherein the obturator includes a stop adjacent the proximal end of the elongate member, and wherein the

obturator is inserted in the cannula until the stop abuts the proximal end of the cannula.

- 5 28. A method according to claim 25, wherein the obturator includes a grip at the proximal end of the elongate member, and further comprising the step of removing the obturator by the grip after the cannula has been inserted in to the percutaneous aperture

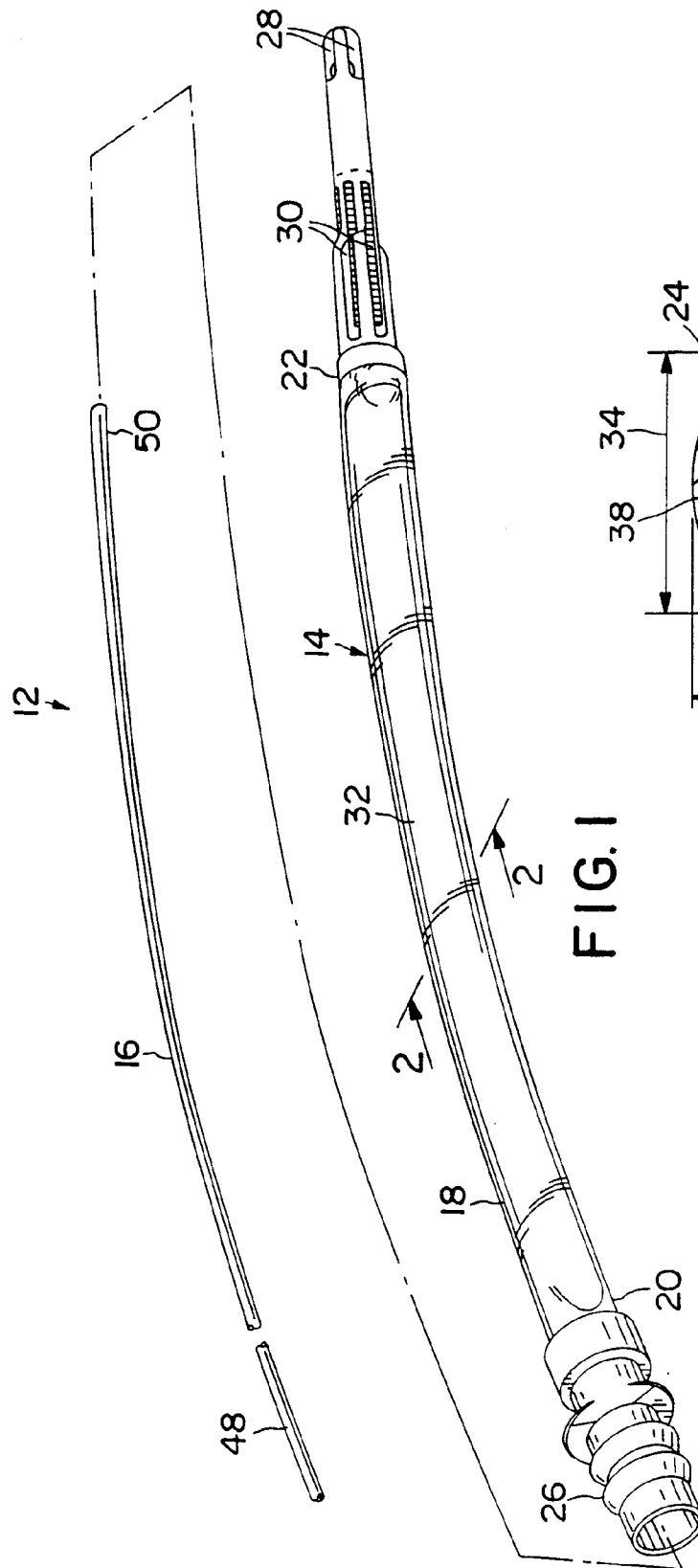


FIG. 1

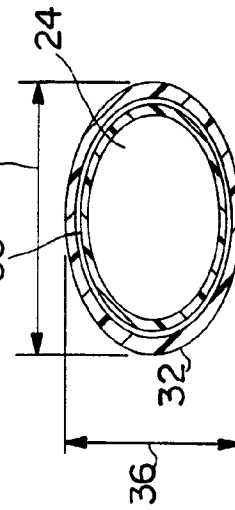


FIG. 2

SUBSTITUTE SHEET (RULE 26)

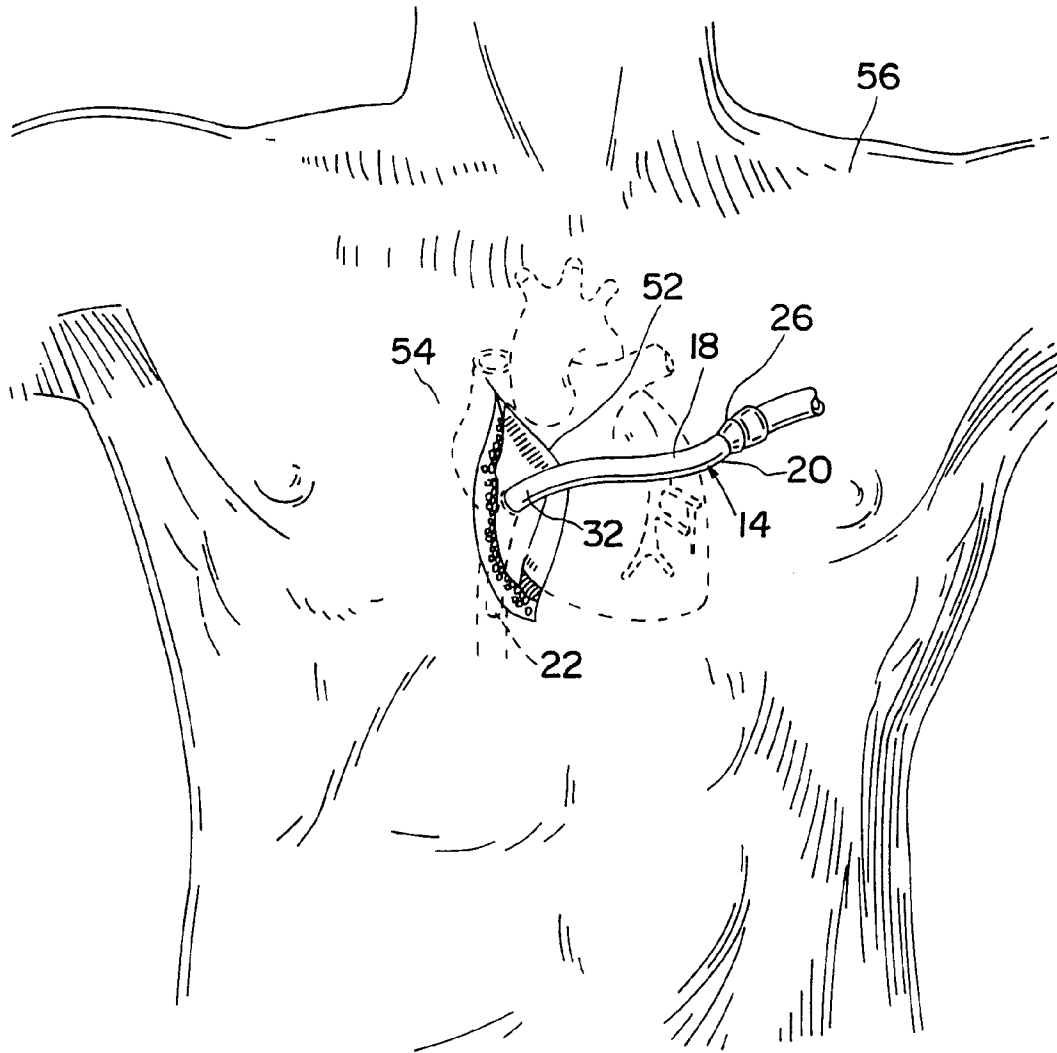


FIG. 3

SUBSTITUTE SHEET (RULE 26)

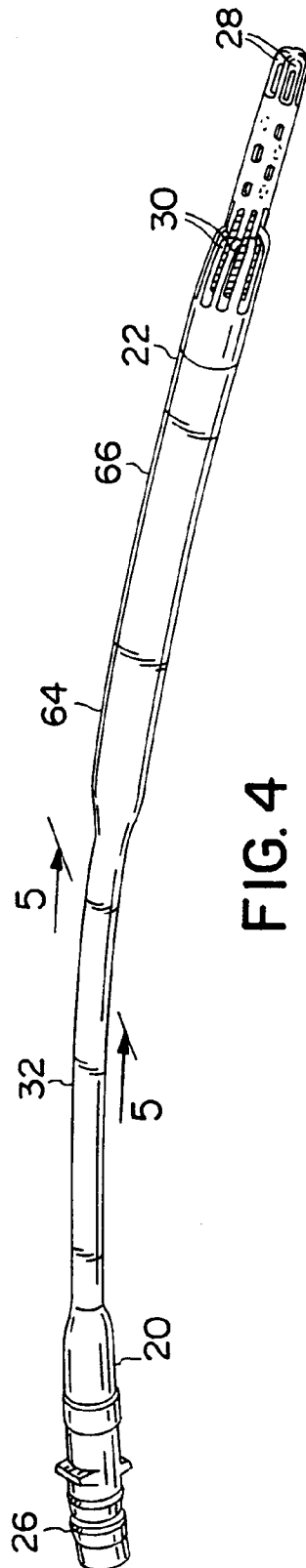


FIG. 4

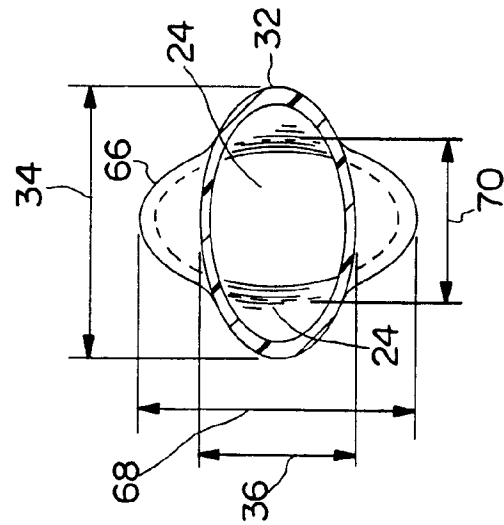


FIG. 5

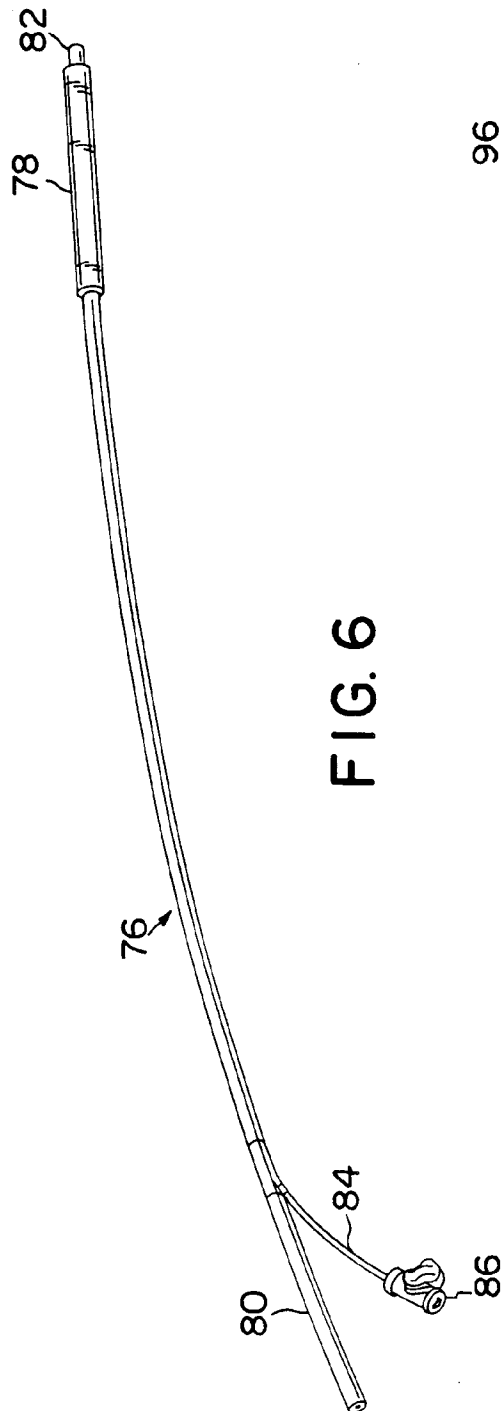


FIG. 6

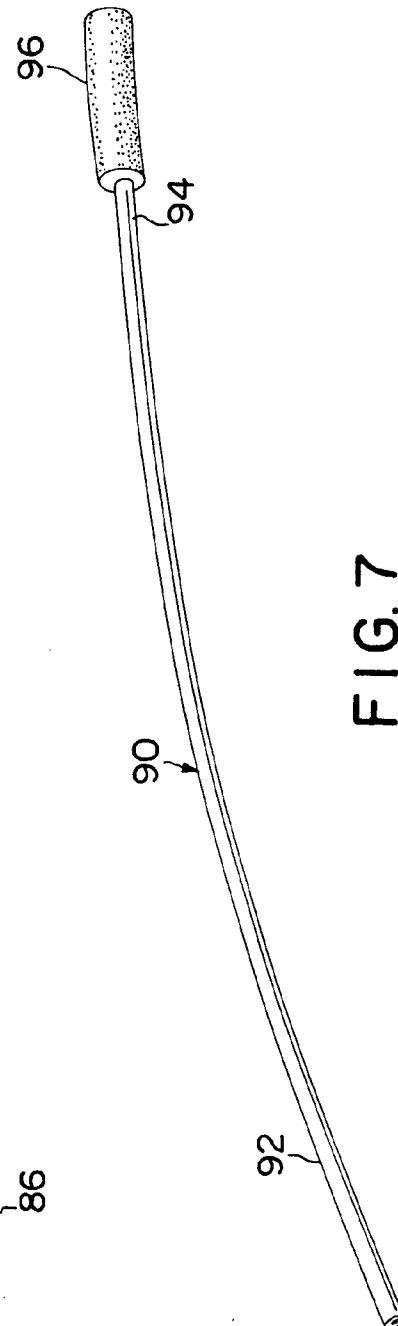
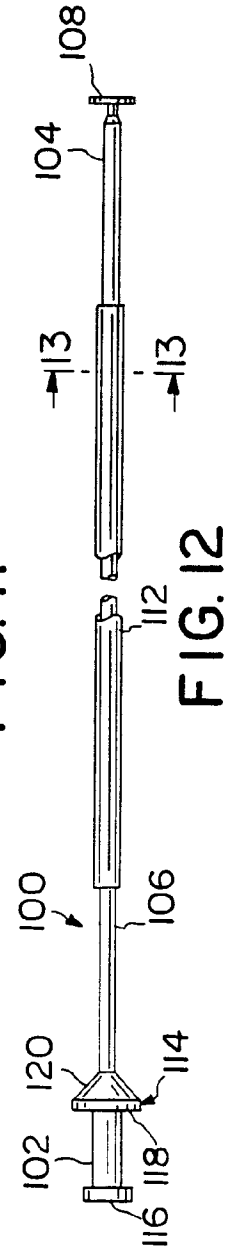
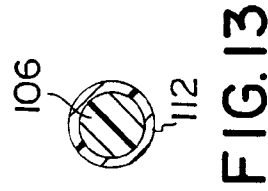
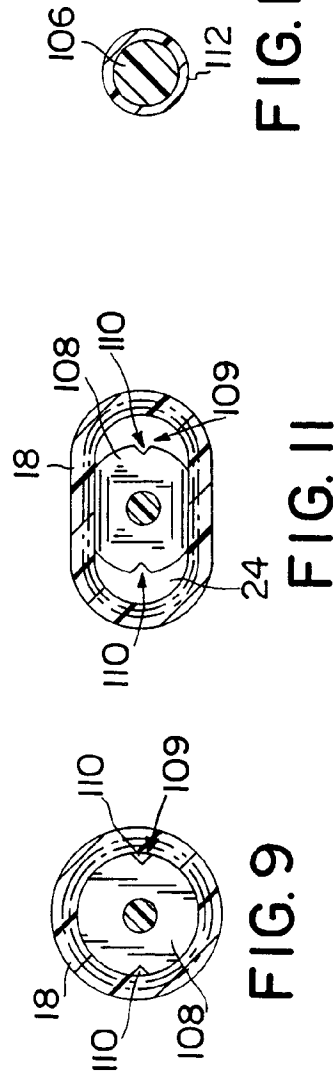
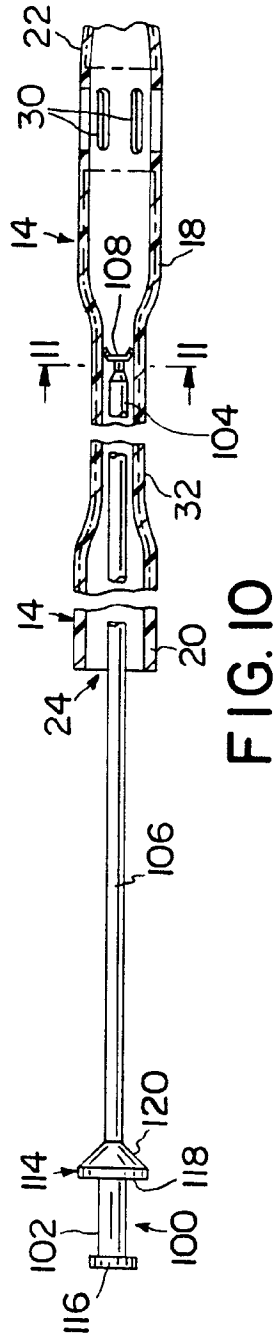
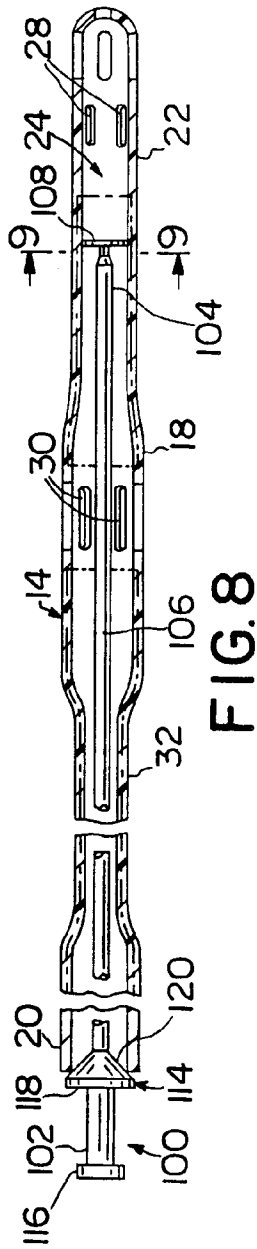


FIG. 7



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/01368

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 804 359 A (GRUNWALD) 14 February 1989 see column 5, line 8 - column 6, line 37; figures ---	1,4,6-8, 10,12, 15,17
Y	US 4 808 158 A (KREUZER) 28 February 1989 see the whole document ---	1,4,6-8, 10,12, 15,17
A	US 4 350 161 A (DAVIS) 21 September 1982 see column 3, line 38 - line 66; figures --- -/--	1,6-8, 10,17,18

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

3 June 1999

Date of mailing of the international search report

10/06/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Kousouretas, I

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/01368

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 201 712 A (BRYANT) 13 April 1993 see column 3, line 22 - column 4, line 27; figures ---	1-4,6, 10, 13-15,17
A	EP 0 300 114 A (BRAUN MELSUNGEN) 25 January 1989 see column 9, line 38 - column 10, line 3; figures ---	1,4-6, 10,15-17
P,A	US 5 817 071 A (DEWINDT) 6 October 1998 see the whole document -----	1,10

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/01368

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 21-28
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/01368

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4804359	A	14-02-1989	NONE	
US 4808158	A	28-02-1989	DE 3523520 A	08-01-1987
			AU 5946286 A	08-01-1987
			DE 3683213 A	13-02-1992
			EP 0212159 A	04-03-1987
			JP 1677939 C	13-07-1992
			JP 3040625 B	19-06-1991
			JP 62079069 A	11-04-1987
US 4350161	A	21-09-1982	US 4432757 A	21-02-1984
US 5201712	A	13-04-1993	NONE	
EP 300114	A	25-01-1989	DE 3721299 A	12-01-1989
			AT 77058 T	15-06-1992
			DE 3871867 A	16-07-1992
			JP 1022262 A	25-01-1989
			US 4871356 A	03-10-1989
US 5817071	A	06-10-1998	AU 5910598 A	03-08-1998
			WO 9830265 A	16-07-1998